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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,475	11/13/2001	Urban Johanson	MEWBURN	3312
110	7590	04/20/2004	EXAMINER	
DANN, DORFMAN, HERRELL & SKILLMAN 1601 MARKET STREET SUITE 2400 PHILADELPHIA, PA 19103-2307			BAUM, STUART F	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/890,475	<b>Applicant(s)</b> JOHANSON ET AL.	
	<b>Examiner</b> Stuart F. Baum	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2004.
- 2a) ☒ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 2,6,11-17,19,29-34 and 37-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7-10,18,20-28,35,36,41 and 42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. The amendment filed 1/30/2004 has been entered.  
  
Claims 1-42 are pending.  
  
Claims 41 and 42 are newly added.  
  
Claims 2, 6, 11-17, 19, 29-34, 37-40 have been withdrawn from consideration because they are drawn to non-elected inventions.
2. Claims 1, 3-5, 7-10, 18, 20-28, 35-36, and 41-42 are examined in the present office action.
3. Rejections and objections not set forth below are withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

***Lack of Unity***

5. Applicant's arguments filed 1/30/2004 have been fully considered but they are not persuasive. Applicants contend that claim 1 as filed is directed to an isolated nucleic acid obtainable from the FRI locus of a plant. The CONSTANS gene described by Simon et al does not reside at this locus and thus this reference cannot be said to read on the subject matter claimed.

Applicant is advised that the proper recourse after the restriction is made final is to petition.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 27 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27, line 5, uses improper Markush phraseology. Inserting the word: --and-- before the word "a", will obviate the rejection. Applicant is directed to the MPEP 2173.05(h) for a more detailed explanation of Markush Group phraseology.

Claim 36 recites the limitation "wherein the nucleic acid ". There is insufficient antecedent basis for this limitation in the claim.

Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: transforming a plant cell with a nucleic acid, regenerating said plant cell into a plant wherein expression of said nucleic acid delays flowering.

***Written Description***

7. Claims 1, 5, 7-10, 18, 20-28, and 35 remain rejected and claims 41 and 42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This

rejection is maintained for the reasons of record set forth in the Official action mailed 8/27/2003. Applicant's arguments filed 1/30/2004 have been fully considered but they are not persuasive.

Applicants contend that they are in possession of genomic DNA from FRI as disclosed in SEQ ID NO:2, FRIGIDA cDNA as disclosed in SEQ ID NO:3 and the amino acid sequence as provided in the specification (page 17, 4<sup>th</sup> paragraph). Applicants contend that methods of identifying sequences exhibiting less than 100% sequence identity with SEQ ID NO:2, which would constitute variants, are well known in the art (page 17, last paragraph). Applicants list examples such as mutagenesis of known sequences, homology searching, and identifying naturally-occurring variants. Applicants contend that the functional limitation in the claim limits the scope of the claim to only those sequences that encode a protein with "proper activity" (page 18, top paragraph). Applicants' response to the objection that the application does not disclose a representative number of variants is that the invention is defined with reference to a given sequence and a function. Applicants again contend that a skilled person can identify variants falling within the scope of the claims by utilizing routine methods (page 18, middle paragraph). Applicants contend that they should be allowed claims that cover the disclosed sequence plus very similar variants (page 18, last paragraph). Applicants contend that new claim 42 relates to variants and is based on highly stringent hybridization conditions as defined on page 12, lines 4-10 of the specification (page 19, 1<sup>st</sup> full paragraph).

The Office contends that Applicants have fulfilled the written description requirements for claims drawn to the full sequence as set forth in SEQ ID NO:1 and SEQ ID NO:2. Applicants have not fulfilled the written description requirements for claim drawn to variants of said sequences, nor sequences that hybridize under stringent conditions to SEQ ID NO:2.

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Applicants have not fulfilled the written description requirements as specified in *Eli Lilly* which include disclosing a representative number of sequences that would identify the genus of sequences, disclosing domains that are important for the activity of the protein and domains that are characteristic of the claimed polypeptide. In addition, Applicants have not disclosed the function of the claimed invention but rather, have stated that overexpression delays flowering. That is not a specific function of the claimed polypeptide. Many proteins when overexpressed delay flowering. Applicants have not presented any examples of variants of SEQ ID NO:2 or SEQ ID NO:1 or sequences that hybridize under stringent conditions to the complement of SEQ ID NO:2 that when overexpressed in a plant delay flowering.

### ***Enablement***

8. Claims 1, 3-5, 7-10, 18, 20-28, 35-36 remain rejected and 41-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 8/27/2003. Applicant's arguments filed 1/30/2004 have been fully considered but they are not persuasive.

Applicants contend that the effects of the FRI locus nucleic acid have been studied and are known to affect flowering time (page 20, 1<sup>st</sup> full paragraph). Applicants contend that the application provides instructions on how to transform plants with the claimed sequences and how to measure flowering time (page 20, 2<sup>nd</sup> paragraph). Applicants also contend that transformation produces variable effects but this is inherent to biological systems. Applicants contend that in

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the present case, the experimentation necessary to achieve the desired result is merely routine (paragraph bridging pages 20 and 21). Applicants contend that an application need not demonstrate the operability of each and every species covered by a claim and that patentable claims may cover inoperable species (page 21, 1<sup>st</sup> full paragraph). Applicants contend that the Clarke et al reference discloses that the FRI locus is a major determinant of flowering time and that enhancers, suppressors and other factors that affect flowering time as disclosed by Clarke et al could be controlled by those skilled in the art who want to use the claimed invention (page 21 2<sup>nd</sup> and 3<sup>rd</sup> paragraphs). Lastly, Applicants contend that the skilled person can readily obtain variants of SEQ ID NO:2 by for example, mutagenesis. The skilled artisan can then test the mutant sequences for function (page 22, 1<sup>st</sup> full paragraph).

The Office contends that Applicants have not reduced to practice the claimed invention. Applicants have taught that breeding studies have shown that the FRIGIDA locus is responsible for variation in flowering time in natural ecotypes of Arabidopsis, but that in the Landsberg erecta ecotype, a dominant FLC allele of the FLC locus is required for the FRI locus to have an affect (page 2, lines 1-21 of the specification). Applicants have not transformed a plant with the claimed invention to generate a plant with delayed flowering. Even though the techniques would be known to one skilled in the art, undue trial and error experimentation would be required to generate a plant with the claimed phenotype using the multitude of sequences that are encompassed by Applicants' claims. Given all the enhancers and suppressors of flowering as disclosed by Clarke et al, Applicant has not even demonstrated that transforming a plant with SEQ ID NO:2 will produce the claimed effect. See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea

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does not constitute [an] enabling disclosure”, and that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention. Lastly, the Office contends that Applicants have not disclosed a biochemical assay to test for the function of the claimed invention.

***102(b) Rejection***

9. Claims 1, 3-5, 7, 9-10, 18, 20, and 22-23 remain rejected under 35 U.S.C. 102(b) as being anticipated by Schmidt et al (1995, Science 270:480-483). This rejection is maintained for the reasons of record set forth in the Official action mailed 8/27/2003. Applicant’s arguments filed 1/30/2004 have been fully considered but they are not persuasive.

Applicants contend that a 102(b) rejection is warranted only when the cited reference identically discloses the subject matter of the invention as claimed. Applicants contend that the Schmidt et al reference does not disclose an identical invention (page 23, 2<sup>nd</sup> paragraph). Applicants contend that Schmidt et al do not explicitly identify any nucleic acid isolate that is capable of accelerating or delaying flowering time. Applicants contend that it cannot fairly be said that this invention was described in a printed publication because the skilled person reading Schmidt et al would not be made aware of nucleic acid encoding a polypeptide that delays or accelerates flowering time. Applicants contend that the Schmidt et al contain no indication that the YAC clones contain any sequence capable of affecting flowering time (page 23, 4<sup>th</sup> paragraph). Applicants contend that the nucleic acid is only obtainable because of the disclosure in the present application.

The Office contends that Applicants’ claims are drawn to a nucleic acid sequence of SEQ ID NO:2 encoding the polypeptide of SEQ ID NO:1. Schmidt et al disclose a sequence



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isolated from Arabidopsis that comprise said sequence, and as such anticipate Applicants' claimed nucleic acid sequence. It is an inherent property of the claimed sequence to delay flowering time when said nucleic acid sequence is transformed into a plant. Given that Applicants' claims are drawn to a product, i.e., the nucleic acid sequence, Schmidt et al disclose Applicants' product. As a note, the Schmidt et al reference, would not anticipate claims drawn to a method of delaying flowering comprising transforming a plant with said nucleic acid sequence.

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.  
Patent Examiner  
Art Unit 1638  
April 6, 2004



AMY J. NELSON, PH.D  
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